

EXHIBIT 1



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Amendment under 37 CFR 1.116 (6 pages); and Exhibit 1 (6 pages).

Invention: VACCINES AGAINST EIMERIA MEDIATED
DISORDERS
Applicant(s): Vermeulen et al.
Filing Date: April 8, 1998
Serial No.: 09/056,806
Date Sent: August 5, 2002 via Express Mail Label No.
Docket No.: 1963-5106US
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Vermeulen et al.

Serial No.: 09/056,806

Filed: April 8, 1998

For: VACCINES AGAINST EIMERIA
MEDIATED DISORDERS

Examiner: S. Turner, Ph.D.

Group Art Unit: 1647

Attorney Docket No.: 5106US

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AMENDMENT UNDER 37 CFR 1.116
EXPEDITED PROCEDURE - EXAMINING GROUP 1647

Box AF
Commissioner for Patents
Washington, D.C. 20231

Sir:

Responsive to the Office Action mailed May 20, 2002, please amend the referenced application as follows:

IN THE CLAIMS:

Please cancel claims 6 through 11, 18, 21 through 26, 29 and 31 without prejudice or disclaimer.

1. (Amended six times) A composition free of whole *Eimeria* parasites, which comprises at least one protein or antigenic fragment thereof, wherein said protein:
 - (a) is present in the hydrophilic phase of a tertooctylphenoxy poly (ethoxyethanol) extract of total *Eimeria* sporozoites; and
 - (b) has a molecular mass of about 26-30 kDa as determined by SDS-PAGE under reducing conditions.

Remarks

The Office Action mailed 20 May 2002, has been received and reviewed. Claims 1 through 15, 18, 19, and 21 through 32 are pending. Claims 6 through 11, 18, 21 through 26, 29 and 31 have been withdrawn from consideration and are canceled herein without prejudice or disclaimer. Claims 1 through 5, 12 through 15, 19, 27, 28, 30 and 32 stand rejected. The application is proposed to be amended as set forth herein. All amendments and cancellations are made without prejudice or disclaimer. Reconsideration is respectfully requested.

March 21, 2002 Supplemental Amendment

Applicants note that the Office Action is responsive to the communication filed on February 21, 2002. However, applicants filed a Supplemental Amendment on March 21, 2002. A copy of the Supplemental Amendment and confirmation of transmission is attached hereto as Exhibit 1. Unfortunately, however, the Supplemental Amendment apparently never made it to the Examiner. For the convenience of the Office, applicants have incorporated the content of the March 21, 2002 Supplemental Amendment herein.

Restriction Requirement

Claims 6 through 11, 18, 21 through 26, 29 and 31 were withdrawn as being drawn to a non-elected invention. Applicants have accordingly canceled these claims in order to place the application in condition for allowance.

Interview

Applicants wish to thank the Examiner for the courtesy extended during the personal interview conducted March 21, 2002. The applicants found this interview especially productive as evidenced by the Interview Summary (Paper No. 19),

Applicants proposed amendment would appear to overcome the rejections of record. However, the newly proposed claim will require further search and consideration to determine patentability.

(Paper No. 19).

Rejections in view of Cited References

Claims 1 through 5, 12 through 15, 19, 27, 28, 30 and 32 stand rejected under 35 U.S.C. §102(b) as being anticipated by EP0382531 to Gurnett. Claims 14 and 28 also stand rejected under 35 U.S.C. §103(a) as being unpatentable under EP0382531 to Gurnett, U.S. Patent 4,981,684 to MacKenzie et al. and U.S. Patent 5,597,807 to Estrada et al. Applicants respectfully traverse the rejections.

Applicants' propose amended claim 1 recites a protein present "in the hydrophilic phase of a tertoctylphenoxy poly (ethoxyethanol) extract of total *Eimeria* sporozoites". Support for the amendment can be found in the specification, for example, on page 23, lines 12 through the end. As discussed at the Interview and confirmed in the Interview Summary, the proposed amendment more clearly defines the invention and distinguishes over the prior art of record.

As agreed at the interview, the primary reference, Gurnett, does not disclose comprising a protein present in the hydrophilic phase of a tertoctylphenoxy poly (ethoxyethanol) extract of total *Eimeria* sporozoites. Gurnett teaches first reacting the sporozoites with a lipase, then conducting a phase separation including. Accordingly, claim 1 distinguishes over the reference. Claims 14 and 28 depend from claim 1 and avoid the prior art, at least, for substantially the same reasons.

Applicants submit that the proposed amendment to claim 1 should be entered because the amendment is supported by the as-filed specification and drawings and do not add any new matter to the application. Also, applicants tried to earlier submit it, but, evidently, the fax did not make it to the Examiner through no fault of applicants. Further, the amendments do not raise new issues or require a further search. Finally, if the Examiner determines that the amendment does not place the application in condition for allowance, entry is respectfully requested upon filing of a Notice of Appeal herein. Reconsideration of the rejection is requested.

Conclusion

In view of the amendments and remarks presented herein, applicants respectfully submit that claims 1-5, 12-15, 19, 27, 28, 30 and 32, are allowable, and an early notice thereof is respectfully solicited. If questions should remain after consideration of the foregoing, the Examiner is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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Date: August 4, 2002

Attachment: Marked up version of the amended claims

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended six times) A composition free of whole *Eimeria* parasites, which comprises [one or more proteins, or fragments] at least one protein or antigenic fragment thereof, wherein said protein [proteins]:

(a) [are] is present in the hydrophilic phase of a tertooctylphenoxypoly (ethoxyethanol) extract of total *Eimeria* sporozoites; and

(b) [have] has a molecular mass [masses] of about 26-30 kDa [\pm 5 kDa when] as determined by SDS-PAGE under reducing conditions[;

and wherein said composition consists essentially of proteins which are non-membrane-bound in *Eimeria*].